

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 23.12.2024

Version: 1



Revision: 10.05.2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** anaxGum opaquer PO
- **Article number:** 25001003, 25002003
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Masking material
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
anax dent GmbH, Dreifelderstr.5, D-70599 Stuttgart
Tel.: 0711/620092-0 Fax: 0711/620092-29
anaxdent.com
- **Further information obtainable from:** R&D, MANI MEDICAL GERMANY GmbH, Tel: +049 6003/8286-0
- **1.4 Emergency telephone number:**
+49 (0) 6003 82 86-0, MANI MEDICAL GERMANY GmbH (8:00 - 17:00) or
+49 (0) 6131 19240 Poison Information Center, University Mainz (24 h)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
 - **Classification according to Regulation (EC) No 1272/2008**
Acute Tox. 4 H332 Harmful if inhaled.
Skin Sens. 1 H317 May cause an allergic skin reaction.
Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

 - **2.2 Label elements**
 - **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
 - **Hazard pictograms**
- 

- GHS07 GHS09
- **Signal word** Warning
 - **Hazard-determining components of labelling:**
2-[[butylamino)carbonyl]oxy]ethyl acrylate
di-urethane dimethacrylate
diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide
 - **Hazard statements**
H332 Harmful if inhaled.
H317 May cause an allergic skin reaction.
H411 Toxic to aquatic life with long lasting effects.
 - **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves.
P304+P340 **IF INHALED:** Remove person to fresh air and keep comfortable for breathing.
P312 Call a POISON CENTER/doctor if you feel unwell.
P321 Specific treatment (see on this label).
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
 - **Additional information:**
Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist.

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- Labelling of packages where the contents do not exceed 125 ml
- Hazard pictograms



GHS07 GHS09

- Signal word *Warning*
- Hazard-determining components of labelling:
2-[[*(butylamino)carbonyl*]oxy]ethyl acrylate
di-urethane dimethacrylate
diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide
- Hazard statements
H317 *May cause an allergic skin reaction.*
- Precautionary statements
P261 *Avoid breathing dust/fume/gas/mist/vapours/spray.*
P280 *Wear protective gloves.*
P321 *Specific treatment (see on this label).*
P501 *Dispose of contents/container in accordance with local/regional/national/international regulations.*
- 2.3 Other hazards
- Results of PBT and vPvB assessment
- PBT: *Not applicable.*
- vPvB: *Not applicable.*

SECTION 3: Composition/information on ingredients

- 3.2 Mixtures
- Description: *Liquid based on methacryl acid ester, containing an activator.*

· Dangerous components:

CAS: 41137-60-4	di-urethane dimethacrylate ⚠ Aquatic Chronic 2, H411; ⚠ Skin Sens. 1B, H317	10-25%
CAS: 63225-53-6	2-[[<i>(butylamino)carbonyl</i>]oxy]ethyl acrylate ⚠ Acute Tox. 4, H332; ⚠ Skin Sens. 1A, H317	2.5-10%
CAS: 10373-78-1	dl-bornane-2,3-dione ⚠ Skin Irrit. 2, H315; ⚠ Eye Irrit. 2, H319; STOT SE 3, H335	<2.5%
CAS: 75980-60-8 EINECS: 278-355-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide ⚠ Repr. 2, H361f; ⚠ Aquatic Chronic 2, H411; ⚠ Skin Sens. 1B, H317	<2.5%

· SVHC

75980-60-8 | diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide

- Additional information *For the wording of the listed hazard phrases refer to section 16.*

SECTION 4: First aid measures

- 4.1 Description of first aid measures
- General information *Immediately remove any clothing soiled by the product.*
- After inhalation *Supply fresh air.*
- After skin contact
If skin irritation continues, consult a doctor.
Immediately wash with water and soap and rinse thoroughly.
- After eye contact
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- After swallowing
Rinse out mouth and then drink plenty of water.

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- Do not induce vomiting; call for medical help immediately.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents** CO₂, powder or water spray. Fight larger fire with alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents** Water with full jet.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:**
Do not inhale explosion gases or combustion gases.
Mount respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation
Keep people at a distance and stay on the windward side.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
- **6.4 Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:**
Storage between 10 °C and 25 °C.
Close container immediately after use and protect product from light incidence.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.

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- **8.2 Exposure controls**
- **Appropriate engineering controls** *No further data; see section 7.*
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures**
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
- **Respiratory protection:** *Not necessary if room is well-ventilated.*
- **Hand protection** *Protective gloves.*
- **Material of gloves**
Butyl rubber, BR
Nitrile rubber, NBR
- **Penetration time of glove material**
0,3 mm
Penetration time 60 min.
0,11 mm
Penetration time 10 min.
- **Eye/face protection** *Safety glasses*

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** *Fluid*
- **Colour:** *According to product specification*
- **Odour:** *Weak, characteristic*
- **Odour threshold:** *Not determined.*
- **Melting point/freezing point:** *undetermined*
- **Boiling point or initial boiling point and boiling range** *undetermined*
- **Flammability** *Not applicable.*
- **Lower and upper explosion limit**
- **Lower:** *Not determined.*
- **Upper:** *Not determined.*
- **Flash point:** *Not applicable*
- **Auto-ignition temperature:** *400 °C (68611-44-9 Siliciumdioxid synthetisches röntgenamorphes)*
- **Decomposition temperature:** *Not determined.*
- **pH** *Mixture is non-soluble (in water).*
- **Viscosity:**
- **Kinematic viscosity** *Not determined.*
- **dynamic:** *Not determined.*
- **Solubility**
- **Water:** *Not miscible or difficult to mix*
- **Partition coefficient n-octanol/water (log value)** *Not determined.*
- **Vapour pressure:** *Not determined.*
- **Density and/or relative density**
- **Density:** *Not determined*
- **Relative density** *Not determined.*
- **Vapour density** *Not determined.*
- **9.2 Other information**
- **Appearance:**
- **Form:** *Pasty*
- **Important information on protection of health and environment, and on safety.**
- **Ignition temperature:** *Product is not selfigniting.*
- **Explosive properties:** *Product does not present an explosion hazard.*

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- **Change in condition**
- **Evaporation rate** *Not determined.*

- **Information with regard to physical hazard classes**
- **Explosives** *Void*
- **Flammable gases** *Void*
- **Aerosols** *Void*
- **Oxidising gases** *Void*
- **Gases under pressure** *Void*
- **Flammable liquids** *Void*
- **Flammable solids** *Void*
- **Self-reactive substances and mixtures** *Void*
- **Pyrophoric liquids** *Void*
- **Pyrophoric solids** *Void*
- **Self-heating substances and mixtures** *Void*
- **Substances and mixtures, which emit flammable gases in contact with water** *Void*
- **Oxidising liquids** *Void*
- **Oxidising solids** *Void*
- **Organic peroxides** *Void*
- **Corrosive to metals** *Void*
- **Desensitised explosives** *Void*

SECTION 10: Stability and reactivity

- **10.1 Reactivity** *No further relevant information available.*
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **10.3 Possibility of hazardous reactions** *Exothermic polymerization*
- **10.4 Conditions to avoid** *No further relevant information available.*
- **10.5 Incompatible materials:**
In presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.
- **10.6 Hazardous decomposition products:** *No dangerous decomposition products known*

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** *Harmful if inhaled.*
- **LD/LC50 values relevant for classification:**
tetramethylene dimethacrylate LD-50 oral > 5000 mg/kg (rat)
- **Primary irritant effect:**
- **Skin corrosion/irritation** *Based on available data, the classification criteria are not met.*
- **Serious eye damage/irritation** *Based on available data, the classification criteria are not met.*
- **Respiratory or skin sensitisation** *May cause an allergic skin reaction.*
- **Germ cell mutagenicity** *Based on available data, the classification criteria are not met.*
- **Carcinogenicity** *Based on available data, the classification criteria are not met.*
- **Reproductive toxicity** *Based on available data, the classification criteria are not met.*
- **STOT-single exposure** *Based on available data, the classification criteria are not met.*
- **STOT-repeated exposure** *Based on available data, the classification criteria are not met.*
- **Aspiration hazard** *Based on available data, the classification criteria are not met.*

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· 11.2 Information on other hazards

· Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

· 12.1 Toxicity

· **Aquatic toxicity:** No further relevant information available.

· **12.2 Persistence and degradability** No further relevant information available.

· **12.3 Bioaccumulative potential** No further relevant information available.

· **12.4 Mobility in soil** No further relevant information available.

· 12.5 Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

· 12.7 Other adverse effects

· **Remark:** Harmful to fish

· Additional ecological information:

· General notes:

Harmful to aquatic organisms

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water.

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

After prior treatment product has to be disposed of in an incinerator for hazardous waste adhering to the regulations pertaining to the disposal of particularly hazardous waste.

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· Uncleaned packaging:

· Recommendation:

Packagings that may not be cleansed are to be disposed of in the same manner as the product.

· **Recommended cleansing agents:** Alcohol

SECTION 14: Transport information

· 14.1 UN number or ID number

· **ADR, IMDG, IATA**

UN3082

· 14.2 UN proper shipping name

· **ADR**

3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (di-urethane dimethacrylate, 2-[[[(butylamino)carbonyl]oxy]ethyl acrylate)

· **IMDG**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (di-urethane dimethacrylate, 2-[[[(butylamino)carbonyl]oxy]ethyl acrylate), MARINE POLLUTANT

· **IATA**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (di-urethane dimethacrylate, 2-[[[(butylamino)carbonyl]oxy]ethyl acrylate)

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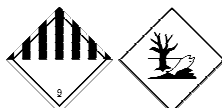
· 14.3 Transport hazard class(es)

· ADR



· Class 9 (M6) Miscellaneous dangerous substances and articles.
 · Label 9

· IMDG, IATA



· Class 9 Miscellaneous dangerous substances and articles.
 · Label 9

· 14.4 Packing group

· ADR, IMDG, IATA III

· 14.5 Environmental hazards:

· Marine pollutant: No
 Symbol (fish and tree)
 · Special marking (ADR): Symbol (fish and tree)
 · Special marking (IATA): Symbol (fish and tree)

· 14.6 Special precautions for user

Warning: Miscellaneous dangerous substances and articles.
 · Hazard identification number (Kemler code): 90
 · EMS Number: F-A,S-F
 · Stowage Category A

· 14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

· Transport/Additional information:

· ADR

· Limited quantities (LQ) 5L
 · Excepted quantities (EQ) Code: E1
 Maximum net quantity per inner packaging: 30 ml
 Maximum net quantity per outer packaging: 1000 ml
 · Transport category 3
 · Tunnel restriction code (-)

· IMDG

· Limited quantities (LQ) 5L
 · Excepted quantities (EQ) Code: E1
 Maximum net quantity per inner packaging: 30 ml
 Maximum net quantity per outer packaging: 1000 ml

· UN "Model Regulation":

UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (DI-URETHANE DIMETHACRYLATE, 2-[[[BUTYLAMINO)CARBONYL] OXY]ETHYL ACRYLATE), 9, III

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SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **Seveso category E2** Hazardous to the Aquatic Environment

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t

· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **National regulations**

· **Waterhazard class:** Water hazard class 2 (Self-assessment): hazardous for water.

· **Other regulations, limitations and prohibitive regulations**

· **Substances of very high concern (SVHC) according to REACH, Article 57**

75980-60-8 | diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H361f Suspected of damaging fertility.

H411 Toxic to aquatic life with long lasting effects.

· **Department issuing SDS:** R&D, MANI MEDICAL GERMANY GmbH

· **Contact:** Fr. R.Naveenakumar

· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

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*ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)**ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)**IMDG: International Maritime Code for Dangerous Goods**IATA: International Air Transport Association**GHS: Globally Harmonised System of Classification and Labelling of Chemicals**EINECS: European Inventory of Existing Commercial Chemical Substances**ELINCS: European List of Notified Chemical Substances**CAS: Chemical Abstracts Service (division of the American Chemical Society)**LC50: Lethal concentration, 50 percent**LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**SVHC: Substances of Very High Concern**vPvB: very Persistent and very Bioaccumulative**Acute Tox. 4: Acute toxicity – Category 4**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**Skin Sens. 1: Skin sensitisation – Category 1**Skin Sens. 1A: Skin sensitisation – Category 1A**Skin Sens. 1B: Skin sensitisation – Category 1B**Repr. 2: Reproductive toxicity – Category 2**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3**Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2*

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